

Remarks

Claims 1 through 8 are pending in this case. Pending claims 1 through 8 have been cancelled. New claims 9 through 14 have been added.

Applicants discovered a stable preformulation form of activated protein C (aPC), providing for aPC cryogranules, a process for preparing aPC cryogranules, and a process of preparing an aPC lyophilized formulation from the aPC cryogranules. This invention provides one means of processing commercial scale aPC suitable for storage, handling, and recovery.

On March 24, 2004, a telephone interview concerning this case was conducted between the Examiner and the Attorney for Applicants. The Interview Summary provided by the Examiner fairly reflects the substance of the interview with following exceptions:

- 1) A declaration will be provided by one of the Applicants.
- 2) The declaration will detail the differences between cryogranulation and lyophilization.
- 3) The declaration will show that cryogranulation of aPC is different and not predictable from cryogranulation of other proteins.
- 4) The Examiner views Claims 5 and 6 as process claims for the activated protein C product. As such, the Examiner prefers that these claims be amended to a product-by-process format. Attorney for Applicants agrees to consider these amendments.

REJECTION OF CLAIMS 42 AND 43 UNDER 35 U.S.C. § 102(b)

Claims 5 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Foster *et al.* (U.S. Patent No. 5,516,650). The Examiner indicated in the telephone interview conducted on March 24, 2004 that Claims 5 and 6 are process claims for the activated protein C (aPC) product. As such, the Examiner preferred that these claims be amended to a product-by-process format. Attorney for Applicants agreed to these consider these amendments. According to *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted), "[E]ven though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable event though the prior product was made by a different process." A